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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,132	12/18/2001	Jiban Kumar Chakrabarti	G-12651	4078
25885	7590	04/21/2004	EXAMINER	
ELI LILLY AND COMPANY PATENT DIVISION P.O. BOX 6288 INDIANAPOLIS, IN 46206-6288			COLEMAN, BRENDA LIBBY	
			ART UNIT	PAPER NUMBER
			1624	

DATE MAILED: 04/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/023,132	CHAKRABARTI ET AL.	
	Examiner	Art Unit	
	Brenda Coleman	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 14-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13,25 and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-26 are pending in the application.

Election/Restrictions

1. Applicant's election with traverse of I in Paper filed December 22, 2003 is acknowledged. The traversal is on the ground(s) that the restriction is improper with regard to Groups II-IV. This is not found persuasive because a search of the final product is not inclusive of the intermediates and thus a separate search of each intermediate is independent of the other. None of the rings or ring systems for formula I, II, III and IV are art recognized equivalents.

Note MPEP 2173.05(h) "where a Markush expression is applied only to a portion of a chemical compound, the propriety of the grouping is determined by a consideration of the compound as a whole, and does not depend on there being a community of properties in the members of the Markush expression. Therefore, what should be considered for patentable distinctness is the compound as a whole. Would a whole compound where the compound is a compound of formula IV or formula II be patentably distinct from a whole compound where the compound is olanzapine? If a reference for one would not be a reference for the other, then restriction is considered proper. It is the compound as a whole an amino ester of formula IV vs. 4-amino-2-methyl-10H-thieno[2,3-b][1,5]benzodiazepine of formula II vs. olanzapine, etc., that must be considered for patentable distinctness.

Thus, separate searches in the literature would be required. However, should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of

the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 14-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper filed December 22, 2003.

Reissue Applications

3. The reissue oath/declaration filed with this application is defective (see 37 CFR 1.175 and MPEP § 1414) because of the following: the applicants indicate that there are 34 claims however, it is only seen that there are 26.

4. The original patent, or a statement as to loss or inaccessibility of the original patent, must be received before this reissue application can be allowed. See 37 CFR 1.178.

5. In accordance with 37 CFR 1.175(b)(1), if the claims or specification are further amended during the prosecution of this reissue, a supplemental reissue oath/declaration under 37 CFR 1.175(b)(1) must be received before this reissue application can be allowed. An example of acceptable language to be used in the supplemental oath/declaration is as follows:

“Every error in the patent which was corrected in the present reissue application, and is not covered by a prior oath/declaration submitted in this application, arose without any deceptive intention on the part of the applicant.”

6. Applicant is notified that any subsequent amendment to the specification and/or claims must comply with 37 CFR 1.173(b).

7. The amendment filed December 18, 2001 proposes amendment to claim 1 that does not comply with 37 CFR 1.173(b), which sets forth the manner of making amendments in reissue applications. A supplemental paper correctly amending the reissue application is required.

- a) Claim 1 step C) is a method of preparing 4-amino-2-methyl-10H-thieno[2,3-b][1,5]benzodiazepine hydrochloride..., which does not appear as it does in claim 1 of U.S. 6,008,216. Step C) should read C) is a method of preparing 4-amino-2-methyl-10H-thi[o]eno[2,3-b][1,5]benzodiazepine hydrochloride.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

8. Claims 25 and 26 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- a) Claims 25 and 26 are vague and indefinite in that it is not known what is meant by 2-fluoronitrobenze in step B).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1624

9. Claims 2-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over CHAKRABARTI et al., U.S. 4,172,831. The generic process of CHAKRABARTI encompasses the instantly claimed compounds (see Formula V, column 7) as claimed herein. Example 26 differs only in the substitution of the thiophene ring at the 2-position. The preferred embodiment of U.S. '831 defines the substituents of the thiophene ring as a C₁₋₄ alkyl, such as ethyl; the thiophene ring is unsubstituted or the thiophene ring is substituted by an electron withdrawing group such as halogen, nitro, trifluoromethyl or C₂₋₄ alkanoyl. Additional examples spanning columns 5-7 contain examples where the substitution on the thiophene ring is methyl in the 2-position, i.e. lines 16-17, 22-23, 39-40, 61-62, 65-66, 9-10, 11-12, etc. The process of preparing compounds of the instant invention are generically embraced by U.S. '831 in view of the interchangeability of the substitutions of formula II. Thus, one of ordinary skill in the art at the time the invention was made would have been motivated to select for example 2- methyl as well as other possibilities from the generically disclosed alternatives of the reference and in so doing obtain the instant compounds in view of the equivalency teachings outlined above.


10. Claims 2-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over CHAKRABARTI et al., U.S. 4,172,831. The generic process of CHAKRABARTI encompasses the instantly claimed compounds (see Formula V, column 7) as claimed herein. Examples spanning columns 5-7 contain examples which are position isomers of the compounds of the instant invention where the methyl substitution of the thiophene ring is in the 3-position, i.e. lines 33-34, 35-36, 53-54, 59-60, etc. One of ordinary skill in the art at the time the invention was made would have been motivated to substitute the instantly claimed isomer for the known 3-methyl-10-(4'-methyl-1'-piperazinyl)-4H-thieno[2,3-b][1,5]benzodiazepine of US '831. Such

modification would be obvious because such structurally related compounds suggest one another and would be expected to share common properties absent a showing of unexpected results. (See *In re Norris*, 84 USPQ 459, on the obviousness of structural isomers).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 571-272-0674. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Brenda Coleman
Primary Examiner Art Unit 1624
April 14, 2004